

# Notice of Allowability

Application No.

09/753,143

Examiner

Kathleen M Kerr

Applicant(s)

ELLIS ET AL.

Art Unit

1652

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/28/04.
2. ☒ The allowed claim(s) is/are 12,14-17,19,20 and 86-93.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
Kathleen M Kerr  
Primary Examiner  
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## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a non-final rejection (mailed on April 2, 2004), Applicants filed a response and amendment received on May 28, 2004. Said amendment amended Claims 12, 14-16, and 86 and cancelled Claim 11. Thus, Claims 12, 14-17, 19, 20, and 86-93 are pending in the instant Office action and will be examined herein.

### *Priority*

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/175,828 and 08/559,303 filed on October 20, 1998 and November 15, 1995.

### *Withdrawn - Objections to the Specification*

3. Previous objection to the specification for a typographical error is withdrawn by virtue of Applicant's amendment correcting said error.

4. Previous objection to the specification for lacking clarity in Table 1 is withdrawn by virtue of Applicant's amendment and the Examiner's clarification in an informal Examiner's amendment authorized by Applicant (see interview summary July <sup>27</sup>~~26~~, 2004).

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***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

5. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “*BLM* gene” is withdrawn by virtue of Applicant’s amendment drawing all claims to Claim 86 wherein the *BLM* gene is clearly defined.

6. Previous rejection to Claims 11, 12, 14-17, 19-20, and 86-93 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn by virtue of Applicant’s amendment drawing all claims to Claim 86 wherein the method is limited to a human subject.

7. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant’s amendment drawing all claims to Claim 86 wherein the *BLM* gene in the claim is clearly described.

8. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, scope of enablement, is wherein the *BLM* gene is enabled to the full extent of its scope.

**EXAMINER’S AMENDMENT**

9. An examiner’s amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Craig Arnold on September 7, 2004.

*Amendments to the Claims*

10. Delete claim 86 and substitute therefor:

---86. A method for determining whether a human subject is a carrier of a mutated BLM gene comprising:

determining whether said human subject carries a mutated or unmutated BLM gene;

wherein the unmutated BLM gene comprises SEQ ID NO:72 and wherein the mutated

BLM gene comprises one or more of:

- i. a deletion of nucleotides 631-633 of SEQ ID NO:72;
- ii. a substitution of A with T at nucleotide 888 of SEQ ID NO:72;
- iii. an insertion of A after nucleotide 1610 of SEQ ID NO:72;
- iv. a substitution of A with G at nucleotide 2089 of SEQ ID NO:72;
- v. a replacement of nucleotides ATCTGA at position 2281-2286 of SEQ ID NO:72 with nucleotides TAGATTC;
- vi. a substitution of T with C at nucleotide 2596 of SEQ ID NO:72; and
- vii. a substitution of G with C at nucleotide 3238 of SEQ ID NO:72.---

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***Art of Record***

11. The following are cited by the Examiner to complete the record, none of which affects the patentability of the allowed claims:

- a) GenBank Accession Number AAA87850. Bloom's syndrome protein. (November 25, 1995)
- b) GenBank Accession Number U39817. Human Bloom's syndrome protein (BLM) mRNA, complete cds. (November 25, 1995)
- c) Ellis *et al.* The Bloom's syndrome gene product is homologous to RecQ helicases. Cell (November 17, 1995) 83(4): 655-666.
- d) WO 97/17979 is Applicant's International application claiming priority to the U.S. application now USPN 5,824,501.
- e) USPN 6,399,378 (Ward *et al.*) teaches RECQL2 which is equivalent to SEQ ID NO:72 in the instant application.

***Conclusion***

12. Claims 12, 14-17, 19-20, and 86-93 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

September 7, 2004